

510(k) Summary according to 21 CFR 807.92

Applicants Name and Address:

Draeger Medical AG & Co. KG
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Germany

MAR 30 2010

Establishment Registration Number: 9611500

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VP Processes, Quality & Regulatory Affairs

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Date submission was prepared:

March 2010

Device Name:

Trade Name: Infinity Acute Care System Workstation Critical Care
Common Name: Intensive Care Ventilator

General description of the device

The Infinity Acute Care System Workstation Critical Care provides critical-care specific functionality. It is made up of the Infinity Medical Cockpit C500 and the ventilation unit Evita Infinity V500. The optional gas supply unit GS500 can be added. The ventilation unit provides critical-care specific ventilation and monitoring data of ventilation parameters. The Infinity Medical Cockpit is the control and display unit which runs a ventilation application. The patient monitoring data are displayed on the Infinity Medical Cockpit, which is also used to control ventilation settings including alarms. The optional gas supply unit provides compressed air to the ventilation unit in case of central gas failure or in house transport.

Infinity Medical Cockpit

The user interface of the Infinity Acute Care System Workstation Critical Care is the Infinity Medical Cockpit, a standardized display and control unit for the connected monitoring and therapy units.

The Infinity Medical Cockpit is a standard platform, using common hardware, software, and user interface components to facilitate ease of use for clinicians.

Evita Infinity V500

The ventilation unit of the Infinity Acute Care System is a microprocessor-controlled ventilator. The Evita Infinity V500 provides overpressure ventilation and adjustable oxygen concentration with pressure- and volume-controlled automatic and spontaneous breathing modes:

- volume-controlled (**VC**):
 - VC-SIMV (**S**ynchronized **I**ntermittent **M**andatory **V**entilation)
 - VC-AC (**A**ssisted **C**ontrolled)
 - VC-CMV (**C**ontinuous **M**andatory **V**entilation)
 - VC-MMV (**M**andatory **M**inute **V**olume **V**entilation)
- pressure-controlled (**PC**):
 - PC-SIMV (**S**ynchronized **I**ntermittent **M**andatory **V**entilation)
 - PC-SIMV+ (**P**ressure **C**ontrol-biphasic positive airway pressure, spontaneous breathing under continuous positive airway pressure with 2 different pressure levels)
 - PC-AC (**A**ssisted **C**ontrolled)
 - PC-CMV (**C**ontinuous **M**andatory **V**entilation)
 - PC-APRV (**O**ption) (**A**irway **P**ressure **R**elease **V**entilation)
 - PC-PSV (**P**ressure **S**upport **V**entilation)
- Spontaneous (**Spn**):
 - Spn-CPAP/VS (**C**ontinuous **P**ositive **A**irway **P**ressure / **V**entilation **S**upport)
 - Spn-CPAP/PS (**C**ontinuous **P**ositive **A**irway **P**ressure / **P**ressure **S**upport)
 - Spn-PPS (**O**ption) (**P**roportional **P**ressure **S**upport)

Additionally the ventilation unit features special modes to complement the ventilation modes. If breathing of a spontaneously breathing patient stops, **Apnea Ventilation** switches over automatically to volume-controlled mandatory ventilation. **Automatic Tube Compensation ATC** reduces the breathing effort attributable to the tube. By switching on the **flow trigger**, the mandatory strokes are synchronised with the patient's spontaneous breathing attempts. **Inspiratoric termination** determines the duration of inspiration in PS, VS and PPS mode. It defines at which relation (in percent) of max. insp. flow the inspiration ends and the expiration starts. **Auto release** determines the duration of pressure release using in PC-

List of performance testing:

Performance was tested in compliance with following standards:

IEC 60601-1 :2006	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 :2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-12:2001	Medical electrical equipment – Part 2-12: Particular Requirements for the safety of lung ventilators – critical care ventilators
IEC 60601-1-6 :2004	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard - Usability
IEC 60601-1-8:2006	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN ISO 14971:2003	Medical devices - Application of risk management to medical devices
EN ISO 17664:2004	Sterilization of medical devices – information to be provided by the manufacturer for the reprocessing of resterilizable medical devices
FDA Guidance for Ventilators: 1995	



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Dräger Medical AG & Company KG
C/O Ms. Joyce Kilroy
Draeger Medical System, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

MAR 30 2010

Re: K093633

Trade/Device Name: Infinity Acute Care System Workstation Critical Care
Regulation Number: 21CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: March 16, 2010
Received: March 18, 2010

Dear Ms. Kilroy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "for" followed by a stylized flourish.

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 093633

Device Name: Infinity Acute Care System Workstation Critical Care

Indications for Use:

The Infinity Acute Care System Workstations Critical Care consist of monitoring and control displays and additional therapy units. They are intended to be used as integrated, networked, and configurable workstations to provide critical care specific therapy. The Infinity Acute Care System Workstations Critical Care are intended to be used by qualified and trained medical personnel.

The Infinity C Series Medical Cockpits, consisting of the C500 and the C700, are monitoring and control displays for the Infinity Acute Care System (IACS). Medical Cockpits are intended to be used to monitor waveforms, parameter information, and alarms as well as to control settings. The Infinity Series Medical Cockpits are intended to be used in environments where patient care is provided by trained healthcare professionals.

The Evita V500 ventilation unit of the Infinity Acute Care System is intended for the ventilation of adult, pediatric and neonatal patients. Evita V500 offers mandatory ventilation modes and ventilation modes for spontaneous breathing support and airway monitoring. The Evita V500 ventilation unit is used with Infinity C Series Dräger Medical Cockpits. The Evita V500 ventilation unit is intended for use in different medical care areas.


Evita V500 is intended for stationary use in hospitals and medical rooms or for patient transportation within the hospital.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

 Concurrency of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093633